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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,540	01/22/2008	Sofia Patricia Becerra	NIHA-0238	5917
45160	7590	03/24/2011		
OTT- NIH c/o WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891			EXAMINER GUCKER, STEPHEN	
			ART UNIT 1649	PAPER NUMBER
			NOTIFICATION DATE 03/24/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

coffice@woodcock.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/566,540	<b>Applicant(s)</b> BECERRA ET AL.	
	<b>Examiner</b> STEPHEN GUCKER	<b>Art Unit</b> 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-61 and 63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-61,63 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.                                                         | 6) <input type="checkbox"/> Other: ____.                          |

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1, 6, 7, 10, 12, 14-22, 24-26, and 53, drawn to a polynucleotide comprising SEQ ID NO:1, classified in class 536 and subclass 23.5 for example.
- II. Claims 1, 6, 8, 10, 12, 14-22, 24-26, and 53, drawn to a polynucleotide comprising SEQ ID NO:2, classified in class 536 and subclass 23.5 for example.
- III. Claims 1, 6, 9, 10, 12, 14-22, 24-26, and 53, drawn to a polynucleotide comprising SEQ ID NO:4, classified in class 536 and subclass 23.5 for example.
- IV. Claims 1, 3, 5, 6, 10, 14-26, and 53, drawn to an encoding polynucleotide comprising polypeptide SEQ ID NO:3, classified in class 536 and subclass 23.5 for example.
- V. Claims 1, 4, 5, 6, 10, 14-26, and 53, drawn to an encoding polynucleotide comprising polypeptide SEQ ID NO:5, classified in class 536 and subclass 23.5 for example.
- VI. Claims 2, 6, 10, 14-22, and 25-26, drawn to a polynucleotide comprising SEQ ID NO:12, classified in class 536 and subclass 23.5 for example.
- VII. Claims 2, 6, 10, 14-22, and 25-26, drawn to a polynucleotide comprising SEQ ID NO:13, classified in class 536 and subclass 23.5 for example.

Art Unit: 1649

- VIII. Claims 2, 6, 10, 14-22, and 25-26, drawn to an encoding polynucleotide comprising polypeptide SEQ ID NO:14, classified in class 536 and subclass 23.5 for example.
- IX. Claims 2, 6, 10, 14-22, and 25-26, drawn to a polynucleotide comprising SEQ ID NO:15, classified in class 536 and subclass 23.5 for example.
- X. Claims 2, 6, 10, 14-22, and 25-26, drawn to a polynucleotide comprising SEQ ID NO:16, classified in class 536 and subclass 23.5 for example.
- XI. Claims 2, 6, 10, 14-22, and 25-26, drawn to an encoding polynucleotide comprising polypeptide SEQ ID NO:17, classified in class 536 and subclass 23.5 for example.
- XII. Claims 11, 13, 27, 28, 30, 32-34, 53, drawn to a polypeptide comprising SEQ ID NO:3, classified in class 530 and subclass 223 for example.
- XIII. Claims 11, 13, 27, 28, 29, 31-34, 53, drawn to a polypeptide comprising SEQ ID NO:5, classified in class 530 and subclass 223 for example.
- XIV. Claims 35-42 and 54, drawn to an antibody that specifically binds SEQ ID NO:3, classified in class 424 and subclass 130.1 for example.
- XV. Claims 35-42 and 54, drawn to an antibody that specifically binds SEQ ID NO:5, classified in class 424 and subclass 130.1 for example.
- XVI. Claims 43-44, drawn to an assay method using a binding complex, classified in class 435 and subclass 7.1 for example.
- XVII. Claims 45-52, drawn to an assay method using hybridization, classified in class 435 and subclass 4 for example.

Art Unit: 1649

XVIII. Claims 55-61 and 63, drawn to gene therapy, classified in class 514 and subclass 44 for example.

**2.** The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I was anticipated in the prior art as indicated by the International Search report; see WO 01/07628 A. By definition, a special technical feature must be novel over the prior art, so Groups I-XVIII do not relate to a single general inventive concept and therefore lack unity of invention.

**3.** Because these inventions are distinct for the reasons given above, and because the search and examination of these groups are different because they involve separate searches in both the patent and non-patent literature, restriction for examination purposes as indicated is proper because the search and examination of these groups is different and would pose an undue burden to the examiner.

**4.** Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.1741).

**5.** The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of

Art Unit: 1649

the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

**6.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is 571-272-0883.

The examiner can normally be reached on Mondays through Fridays from 0930 to 1800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 1649

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. G./

Examiner, Art Unit 1649

Stephen Gucker

March 15, 2011

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649